REMARKS

Claims 138 and 157 have been amended. Support for the claim amendments may be found at, for example, p. 46, line 25 to p. 47, line 2 of the specification. Applicants respectfully request the consideration of the species Blo t 5 and FveR27A in amended claim 138 once the search for the elected species Der p 2 and FveT29A is complete.

Claims 137-156 and 158-169 have been cancelled without prejudice. Applicants reserve the right to pursue the subject matter of those claims in a continuing application. New claims 170-179 have been added. No new matter has been added. Support for the new claims may be found at, for example, p. p. 39, line 11, 163-165 of the specification and previously filed claims.

Claims 138, 157 and 170-179 are pending.

CLAIM OBJECTIONS

The Examiner has objected to claims 141, 147, 149 and 155-156. See Office Action at p. 3. Claims 141, 147, 149 and 155-156 have been cancelled thus rendering this objection moot with respect to those claims. Applicants respectfully request the withdrawal of this objection.

CLAIM REJECTIONS

Rejection of claims under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 138-141, 147-150 and 154-157 under 35 U.S.C. § 112, second paragraph as being indefinite. See Office Action at p. 4. Not in acquiescence to this rejection but in an effort to expedite prosecution, Applicants have cancelled claims 138-141, 147-150 and 154-156 thus rendering this rejection moot with respect to those claims.

The Examiner has rejected claim 138 as the Examiner contends that claim 138 (and others) "only describe the polypeptides and proteins of interest by arbitrary names." See Office Action at p. 5. The Examiner specifically refers to the phrase "an Fve polypeptide" in claim 138. Applicants have amended claim 138 to clarify that the Fve polypeptide has a sequence shown as SEQ ID NO: 1 and includes a mutation selected from the group consisting of: a mutation from R to A at position 27 of that sequence (R27A) and a mutation from T to A at position 29 of that sequence (T29A). Applicants have retained the terms "Blo t 5" and "Der p 2" and amended the claim to include specific reference to species of house mites from which the particular allergens are derived as well as their Group number. The abbreviations are standard means by which persons skilled in the art refer to allergens, including house mite allergens being claimed. The

claims as amended state the Group of the allergens (i.e., Group 2 or Group 5), which embody the characteristics of the allergens which are used for the group classification. Given this and the reference to the abbreviated polypeptide name (e.g., Der p 2), Applicants submit that a person skilled in the art would know what polypeptides the claims are seeking to protect.

The Examiner additionally rejected claim 138 as the Examiner contends that "it is unclear what sequences have 70% sequence identity to an unspecified sequence." See Office Action at p. 7. Applicants have amended claim 138 and deleted the phrase "a polypeptide having at least 70% sequence identity." Applicants believe claim 138 as amended is clear and concise and respectfully requests the reconsideration and withdrawal of this rejection.

The Examiner has rejected claim 157 for "insufficient antecedent bas[i]s" for the phrase "formed construct." See Office Action at p. 7. Applicants have amended the dependency of claim 157 to provide correct antecedent basis for the term "construct." Applicants respectfully request the withdrawal of this rejection.

Rejection of claims under 35 U.S.C. § 112, first paragraph

Enablement

The Examiner has rejected claims 138-141, 147-150 and 154-157 under 35 U.S.C. § 112, first paragraph, for lack of enablement." See Office Action at p. 8. Not in acquiescence to this rejection but in an effort to expedite prosecution, Applicants have cancelled claims 138-141, 147-150 and 154-156 thus rendering this rejection moot with respect to those claims.

Claim 138 has been amended to recite a method for producing a polypeptide capable of stimulating an immune response against a molecule, the method including (a) identifying a molecule against which the stimulation of the immune response is desired, the molecule selected from the group including a Group 5 allergen of a hose mite of species *Blomia tropicalis* (Blo t 5) or a Group 2 allergen of a house mite of species *Dermatophagoides pteronyssinus* (Der p 2); and (b) forming a fusion protein by joining the molecule as a first portion thereof with a second portion being an Fve polypeptide having a sequence shown as SEQ ID NO: 1 and including a mutation selected from the group including a mutation from R to A at position 27 of that sequence (R27A) and a mutation from T to A at position 29 of that sequence (T29A). These correspond respectively to SEQ ID NO: 46, which the Examiner acknowledges as being enabled by the specification. See Office Action at p. 8.

The claims have further been amended to cover methods of producing fusion protein having as a first portion a Group 5 allergen of a house mite of *Blomia tropicalis* (Blo t 5) and a second portion including the Fve mutants listed above. Applicants submit that this subject matter is equally enabled by the specification. The specification at Examples 13 at page 117 describes the construction of each of the fusion proteins specified in claim 138. A schematic showing fusion proteins, which includes as first portions Blo t 5 or Der p 2 and second portions FveR27A or FveT29A is shown in Figure 16. Figure 17 describes expression of allergen-Fve fusion proteins, while Figures 18, 19, 21, 22, 23 show various results obtained and showing the characteristics of allergen-Fve fusion proteins. These are described in detail at Example 17.

It is clear from the above that the specification describes the invention in sufficient detail to enable a person skilled in the art to make the invention. Applicants therefore submit that Claim 138 and dependent claim 157 is sufficiently enabled by the specification as filed. Applicants respectfully request reconsideration and the withdrawal of this rejection.

Written Description

The Examiner has rejected claims 138-141, 147-150 and 154-157 under 35 U.S.C. § 112, first paragraph, "as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." See Office Action at p. 14. Not in acquiescence to this rejection but in an effort to expedite prosecution, Applicants have cancelled claims 138-141, 147-150 and 154-156 thus rendering this rejection moot with respect to those claims.

The Examiner has acknowledged that "Applicants is in possession of: a method for producing the fusion proteins of SEQ ID NO: 44 and 46." Id. As previously explained, claim 138 has been amended to include methods of producing fusion protein having as a first portion a Group 5 allergen of a house mite of *Blomia tropicalis* (Blo t 5) and a second portion including the Fve mutants listed in claim 138.

As previously pointed out, the specification at Examples 13 at page 117 describes the construction of each of the fusion proteins specified in claim 138. Figure 16 shows fusion proteins, which includes as first portions Blo t 5 or Der p 2 and second portions FveR27A or FveT29A. Figure 17 describes expression of allergen-Fve fusion proteins, while Figures 18-23

show various results obtained and showing the characteristics of allergen-Fve fusion proteins. These figures are described in detail at Example 17.

Accordingly, the specification sufficiently describes the claimed invention in full, clear, concise and exact terms and satisfies the written description requirement of 35 U.S.C. § 112, first paragraph. Thus Applicants respectfully request reconsideration and withdrawal of this rejection with respect to claim 138 and dependent claim 157.

Rejection of claims under 35 U.S.C. § 103

The Examiner has rejected claims 138-141 and 155-157 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Publication No. 2004/0071718 to Tsai ("Tsai") in view of Ko et al., *Journal of the Formosan Medical Association*, Vol. 96, No. 7, pgs. 517-524 (1997) ("Ko"). See Office Action at p. 18. Not in acquiescence to this rejection but in an effort to expedite prosecution, Applicants have cancelled claims 138-141 and 155-156 thus rendering this rejection moot with respect to those claims.

Tsai describes

> [m]ethods and pharmaceutical compositions for treating allergen-induced airway inflammation. The method includes administering a therapeutically effective amount of a pharmaceutical composition comprising a Dermatophoides pteronyssinus group 2 (Dp2) epitope peptide and a pharmaceutically acceptable carrier to an individual having allergen-induced airway inflammation, in a manner consistent with local nasal immunotherapy.

See Abstract. Tsai does not teach or suggest a method for producing a polypeptide capable of stimulating an immune response against a molecule, the method including (a) identifying a molecule against which the stimulation of the immune response is desired, the molecule selected from the group including of: a Group 5 allergen of a hose mite of species *Blomia tropicalis* (Blo t 5) or a Group 2 allergen of a house mite of species *Dermatophagoides pteronyssinus* (Der p 2); and (b) forming a fusion protein by joining the molecule as a first portion thereof with a second portion being an Fve polypeptide <u>having a sequence shown as SEQ ID NO: 1 and including a mutation selected from the group including a mutation from R to A at position 27 of that sequence (R27A) and a mutation from T to A at position 29 of that sequence (T29A)</u>.

Tsai further does not teach or suggest making mutations of Fve polypeptides, let alone the specific R27A or T29A mutations as described in claim 138. There is no indication in Tsai that mutations can improve the beneficial properties of Fve. Therefore, a person skilled in the art

would not have attempted to make Fve mutations, let alone fusion proteins comprising these, with any reasonable expectation of success.

These defects are not remedied in Ko. Ko describes cloning and sequencing of FIP-*fve* cDNA. Ko does not teach or suggest a method for producing a polypeptide capable of stimulating an immune response against a molecule, the method including (a) identifying a molecule against which the stimulation of the immune response is desired, the molecule selected from the group including of: a Group 5 allergen of a hose mite of species *Blomia tropicalis* (Blo t 5) or a Group 2 allergen of a house mite of species *Dermatophagoides pteronyssinus* (Der p 2); and (b) forming a fusion protein by joining the molecule as a first portion thereof with a second portion being an Fve polypeptide having a sequence shown as SEQ ID NO: 1 and including a mutation selected from the group including a mutation from R to A at position 27 of that sequence (R27A) and a mutation from T to A at position 29 of that sequence (T29A).

Accordingly, claims 1138 and claims that depend therefrom are patentable over the combination of Tsai and Ko for at least the reasons described above. Applicants respectfully request reconsideration and withdrawal of this rejection.

Patentability of New claims 170-179

New claims 170-179 depend from independent claim 138. As previously explained, claim 138 is patentable over the combination of Tsai and Ko. As such, dependent claims 170-179 are patentable over Tsai and Ko for at least the reasons described above. Applicants respectfully request the allowance of new claims.

CONCLUSION

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the claims now pending are in condition for allowance. A petition for a one-month extension of time is attached. Should any further fees be required by the present Reply, the Commissioner is hereby authorized to charge Deposit Account **19-4293**.

Respectfully submitted,

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